National Health Care Institute

International strategic agenda 2020

National Health Care Institute

MAY 2020

Contents

1 Introduction 3
1.1 Goals of this international strategic agenda 2020 3
1.2 Focus 3
1.3 The process of producing this ISA 4
1.4 Reader's guide 4

2 ZIN's international strategy for 2020 6
2.1 Why we collaborate with other countries 6
2.1.1 Preserving an affordable health care system: our package management tasks 6
2.1.2 Better care available faster: our quality-of-care tasks 6
2.1.3 Better custom-made decisions based on relevant data: our health care data tasks 6
2.2 How international collaboration benefits our ambitions 7

3 Ambition One: Preserving an affordable health care system 9
3.1 Sub-goal 1: Explaining our processes to the public in an understandable way 9
3.2 Sub-goal 2: Developing alternatives to our dichotomous HTA-system 9
3.2.1 Horizon scanning 9
3.2.2 Real world data (RWD) 10
3.2.3 Registries 10
3.2.4 Collaboration with regulators (EMA) 11
3.2.5 European HTA 11
3.2.6 Mechanisms for pricing of pharmaceuticals and medical devices 12
3.2.7 Price and reimbursement methods 12
3.2.8 Indication-wide assessments 13
3.2.9 Orphan drugs 13
3.2.10 Advanced Therapy Medicinal Products (ATMP's) and genomics 14
3.2.11 Personalised medicine 14
3.2.12 Medical Devices Regulation (MDR) 15
3.3 Sub-goal 3: More appropriate care 16
3.3.1 IZZI network 17
3.3.2 Promoting appropriate introduction of health care innovations 17

4 Ambition Two: Better care available faster 18
4.1 Sub-goal 1: Encourage the use of patient reported data 18
4.1.1 Encouraging the development and implementation of guidelines and indicators 18
4.2 Sub-goal 2: Guidelines should address appropriate care 19
4.2.1 Assessment framework (Toetsingskader) 19
4.3 Sub-goal 3: ZIN's advice process is up-to-date and ready for innovative health interventions 19

5 Ambition Three : Better custom made decisions based on relevant data 21
5.1 Sub-goal 1: Clarify what information is relevant for patients 21
5.2 Sub-goal 2: Unambiguous and reliable information-sharing 21
5.2.1 Interoperability 21
5.2.2 Data strategy 23
5.2.3 Innovation 23
5.3 Sub-goal 3: Focus on information that is relevant for patients 24

6 Networks and projects 25

7 Sources 30

1 Introduction

The Dutch health care system is based on the principles of a high level of access to care solidarity (because everyone is obliged to take out medical health insurance and insurers are obliged to accept all) and high quality health care services. The National Health Care Institute (*Zorginstituut Nederland*, or ZIN) carries out tasks relating to two Dutch statutory health insurance schemes: the Health Insurance Act (*Zorgverzekeringswet*) and the Long-Term Care Act (*Wet langdurige Zorg*, Wlz). ZIN's role in maintaining the quality, accessibility and affordability of health care in the Netherlands involves various tasks. For more information about the tasks and activities of ZIN, see our website.[1]

1.1 Goals of this international strategic agenda 2020

When performing its tasks, ZIN participates with various other countries in an increasing number of international activities. This international strategic agenda (ISA) 2020 has been formulated to maintain focus on these international activities, and to decide which activities are relevant for ZIN and its tasks. The ISA describes relevant topics and international activities for 2020. It also describes ZIN's position on relevant topics. As such, the ISA serves various goals:

- To provide an overview of ZIN's international activities in 2020;
- By describing the relevant topics and corresponding international activities, this ISA is used to determine which international activities (e.g., international networks, projects and conferences) are relevant for ZIN's tasks and activities;
- Describing ZIN's positions on these topics increases colleagues' awareness of these corporate positions. This will increase ZIN's impact in international networks where agendas and joint positions are determined, and during ZIN presentations and workshops at conferences.

Where deemed appropriate, ZIN works together with other Dutch national bodies that focus on health care and that also particate in international activities.[2]

1.2 Focus

The activities described in this ISA focus on 2020. Both national and international developments can have an impact on these international activities. Examples are the upcoming trade deal between the USA and Europe, and Brexit and the COVID-19 pandemic. The consequences of these developments, though as yet unknown, will be taken into account as and when needed. Where necessary, activities will be altered.

The main focus of ZIN's international activities is Europe, although countries outside Europe are not necessarily excluded.

ZIN's long-term research agenda, which was approved by the board of directors in June 2019, describes relevant research topics, based on 3 ambitions and 9 sub-goals as formulated in ZIN's long-term plan for 2018-2022. The structure is therefore the same as this ISA. To avoid overlap, this ISA does not focus on research, but instead describes all relevant topics that ZIN should focus on internationally by, e.g., participating in international networks. When a topic specifically calls for research, it is described as such in ZIN's long-term research agenda.

This ISA focuses specifically on 3 ambitions and on ZIN's tasks. This means that some relevant international topics may not have been mentioned in this ISA, because these topics are not part of ZIN's tasks. For more information about the ambitions, tasks and activities and activities of ZIN, see our website.[3]

1 english.zorginstituutnederland.nl/about-us

2 *for example the Ministry of Health, Welfare and Sport, (Ministerie van Volksgezondheid, Welzijn en Sport, VWS), Dutch Healthcare Authority (Nederlandse Zorgauthoriteit, NZa), Health and Youth Care Inspectorate (Inspectie Gezondheidszorg en Jeugd, IGJ), National Institute for Public Health and the Environment (Rijksinstituut voor Volksgezondheid en Milieu, RIVM), Zorgverzekeraars Nederland (ZN), Centraal Administratie Kantoor (CAK), Medicines Evaluation Board (College ter Beoordeling van Geneesmiddelen, CBG-MEB) and the Netherlands Organisation for Health Research and Development (ZonMw).*

3 english.zorginstituutnederland.nl/about-us

1.3 The process of producing this ISA

This ISA was produced by a project team with members from various backgrounds. After producing a draft version, each member consulted with their colleagues, focusing on specific topics to which they had been assigned.

In Q2 of 2019 ZIN carried out a qualitative study that compared 6 reports from the WHO, RIVM, OECD and EHCI[4] on various European health care systems and how they performed. Where relevant, conclusions of that qualitative study were integrated into this ISA.

Other sources that were taken into account were from EMA[5], NICE[6], IQWiG[7], the permanent representation of the Dutch Ministry of Health, Welfare and Sports in Brussels[8] and the Mission Letter of Ursula von der Leyen (President of the European Commission) to Stella Kyriakides, Commissioner-Designate for Health[9].

After adding and processing the input and feedback from colleagues, the draft version was presented to the Quality Board and the Insured Package Advisory Committee for consultation. The members of that board and commission are external experts in health care and research.

The final version was approved by the board of directors of ZIN in Q2 of 2020.

1.4 Reader's guide

- Chapter 1 describes the introduction and background information. Chapter 2 gives ZIN's vision on its international activities. Chapters 3, 4 and 5 describe various topics in relation to the 3 ambitions described in ZIN's long-term plan for 2018-2022:
- Chapter 3, ambition 1: *Preserving an affordable health care system, for the general public as well as the government.*
- Chapter 4, ambition 2: *Better care available faster by accelerating the cycle of measurement, knowing, learning and implementing in health care.*
- Chapter 5, *ambition 3: The public are able (together with their health care providers) to make better customised decisions about their own health: They will have access to relevant information about the supply of health care, its quality and treatment options.*

4 *1) OECD: 'Health at a Glance: Europe 2018'; 2) EHCI: 'Euro Health Consumer index', 2018; 3) RIVM: 'Het Nederlandse gezondheidszorgsysteem in internationaal perspectief', 2018; 4) WHO: 'Better noncommunicable disease outcomes: challenges and opportunities for health systems', 2014; 5) 'Health systems respond to noncommunicable diseases. Compendium of good practices', 2018; 6) 'Medicines reimbursement policies in Europe', 2018.*

5 *'EMA Regulatory Science to 2025 – Strategic reflection', www.ema.europa.eu/en/documents/regulatory-procedural-guideline/ema-regulatory-science-2025-strategic-reflection_en.pdf*

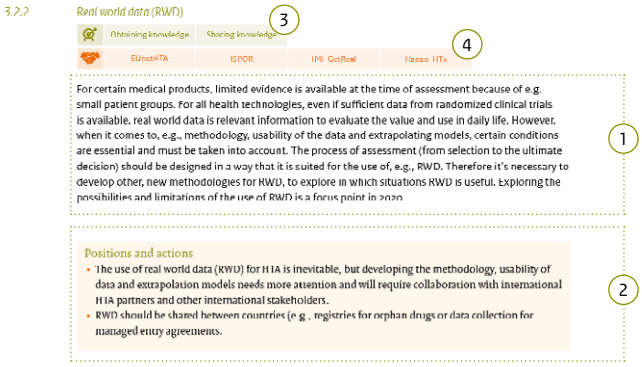
6 *'Business Plan: objectives and performance measures 2019/20', www.nice.org.uk/Media/Default/About/Who-we-are/Corporate-publications/Corporate-and-business-plans/business-plan-19-20.pdf*

7 *'In a nutshell. Facts and figures from IQWiG 2018', www.iqwig.de/en/press/media-centre/flyers-annual-reports-and-brochures.7357.html.*

8 *'The Netherlands' propositions for the EU health agenda 202002025', www.permanentrepresentations.nl/documents/ publications/2019/06/13/the-netherlands'-propositions-for-the-eu-health-agenda-2020-2025*

9 *ec.europa.eu/commission/sites/beta-political/files/mission-letter-stella-kyriakides_en.pdf*

Each topic contains 4 different elements:



1. A short description of the topic and its focus in 2020.
2. The positions of ZIN on that topic (if applicable) and actions that need to be taken in order to steer the topic in the desired direction, i.e. align it with those positions.
3. Participation in international activities can have multiple objectives. However, the most important objective for 2020 for each topic is highlighted. These objectives are explained in the next chapter.
4. A list of international collaborations or projects in which ZIN is participating, that should help achieve the described objective of that specific topic.

A complete list of collaborations and projects in which ZIN is participating, including descriptions, can be found in Chapter 6. Finally, Chapter 7 describes the sources used.

At the end of 2020, the objectives will be evaluated for each topic, including the corresponding international networks. This evaluation will act as input for the ISA for 2021 and, where necessary, international activities will be adjusted.

2 ZIN's international strategy for 2020

This chapter describes why we collaborate internationally and how that helps us achieve our goals. Exactly what activities we do is described in more detail in Chapters 3, 4 and 5.

2.1 Why we collaborate with other countries

Every person in the Netherlands is entitled to health care offered in the basic health insurance package. In order to guarantee the quality, accessibility and affordability of the Dutch health care system, ZIN has set three ambitions for 2018-2022, which are:

1. Preserving an affordable health care system;
2. Making better care available faster;
3. Taking better custom-made decisions based on relevant data.

ZIN's ambitions and their international context are described in the next paragraphs.

2.1.1 *Preserving an affordable health care system: our package management tasks*

When we look at our current international activities (e.g. congresses we visit, international projects we participate in and international collaborations we are part of), we see that roughly 75% of these international activities serve the first ambition, focusing on medicines, prices of medicines, Health Technology Assessments (HTA) and package management (see Chapter 3 for a complete list of our activities focusing on this first ambition). Taking into account the fact that most pharmaceutical companies are international or even global, collaboration with other countries is crucial, as we are stronger if we stand together. Also, the market authorization of new medicines is assessed by the European Medicines Agency, making it a European matter rather than a national one. Lastly, the share of medicines in total health expenditures in the Netherlands (and other countries) is rising due to many new drugs coming onto the market as well as their often high prices, threatening the affordability of health care. Preserving an affordable health care system through for example risk adjustment, focusing on our package management tasks, therefore remains one of our international priorities in 2020.

2.1.2 *Better care available faster: our quality-of-care tasks*

In recent years additional tasks on top of package management have been assigned to ZIN by the Ministry of Health, Welfare and Sport of the Netherlands. From 1 April 2014 onwards, ZIN has been encouraging good health care by helping the stakeholders involved to continually improve the quality of Dutch health care and by helping patients find high-quality care (our second ambition for 2018-2022). The joint consultations involving patients, health care providers and health insurers result in agreements about good health care that are translated into quality standards. If the stakeholders are unable to reach an agreement, whatever the reason, ZIN provides support in creating a quality standard.

Quality of care has been mainly a national matter rather than a European one. Combined with the fact that ZIN's activities relating to the quality of care are relatively new for ZIN, means that ZIN's international activities focusing on quality of care in particular are limited. However, we think it is desirable to have a closer connection with European and international organizations that focus on quality of care, mainly to obtain and share knowledge. Examples of these international organizations are the World Health Organization (WHO) and the Organisation for Economic Co-operation and Development (OECD, particularly the Health Division). A closer connection with these organizations may keep us informed more quickly about international developments in health care, giving us the opportunity to incorporate these developments into our activities and policies sooner, where appropriate and useful. In 2020, we are investigating what kind of link might serve us best for this.

2.1.3 *Better custom-made decisions based on relevant data: our health care data tasks*

More recently, from 1 January 2020 onwards, ZIN has become involved in standardizing and optimizing information sharing between stakeholders in Dutch long-term care, youth care and care provided under the Social Support Act. As with our activities focusing on further improving the quality of care, ZIN's international activities that focus on standardizing and optimizing information sharing in particular (e.g.

through artificial intelligence, better interoperability of data and innovation) are limited. Our activities focusing on this topic are described in Chapter 5.

In 2020, we are investigating what kind of connection might serve us best in these areas. The main goal of joining additional networks would be to obtain knowledge and to see if our activities can benefit from that knowledge. Preparatory to that, a study was conducted at the end of 2019 to get a picture of relevant networks in Brussels that focus on standardizing and optimizing information sharing between stakeholders. The results of this study will be used in 2020 to determine which networks ZIN can benefit from, and to explore whether joining those networks would be useful.

2.2 How international collaboration benefits our ambitions

The COVID-19 pandemic proves how important international collaboration is. When collaborating with others, ZIN believes it is important to have an impact that leads to valuable outcomes. ZIN distinguishes between short-range outcomes (directly influenced by our activities) and long-range outcomes (not directly influenced by our activities). When formulating our activities in the following chapters, we have tried as much as possible to focus on activities that lead to outcomes influenced by our activities, making those activities as effective as possible.

For ZIN, working with other countries can have various benefits, depending on aspects such as the context and topic. We have defined five reasons for international collaboration.

Being stronger together
Collaboration makes the participating countries stronger than when they operate alone. This can for example be helpful in negotiations with large international pharmaceutical companies about prices and conditions of medicines.

Dividing the workload
Another reason is that by working together with other countries allows the workload to be divided between those countries. One example is European HTA, a European project with the goal of exchanging health technology assessment reports instead of doing the same analyses in each country separately.

Influencing policy
Participating in international activities is one way that ZIN tries to influence European policy, leading to new policy that serves the Dutch public best. This is done by co-authoring or providing feedback on policy papers and positioning papers and by contributing to European and other agendas.

Obtaining knowledge
International collaboration can lead to new ideas and inspiration and it can help us keep up to date about the latest developments, even on our front runner activities. Some countries are ahead of the Netherlands or may have innovative ideas or best practices. ZIN can learn from these countries and where possible apply their solutions in the Netherlands by obtaining knowledge about the other's experience. It is also useful to have a picture of reimbursement differences between countries and the reasons behind those differences. Reimbursement decisions are often discussed in the Dutch media and knowing the reimbursement schemes in other countries can create support for our own decisions and can help explaining those decisions to the general public.

In order to stay up to date with European and international trends in health care, ZIN carried out a qualitative study in 2019 that analysed six reports by the WHO, RIVM, OECD and EHCI on various European health care systems and how they are performing[10]. The goal was to see which international findings and trends in these reports are relevant for our activities. This qualitative study will be done again in 2020 (with new reports).

10 *Those reports are 1) OECD: 'Health at a Glance: Europe 2018'; 2) EHCI: 'Euro Health Consumer index', 2018; 3) RIVM: 'Het Nederlandse gezondheidszorgsysteem in internationaal perspectief', 2018; 4) WHO: 'Better non-communicable disease outcomes: challenges and opportunities for health systems', 2014; 5) 'Health systems respond to non-communicable diseases. Compendium of good practices', 2018; 6) 'Medicine reimbursement policies in Europe', 2018.*

As a governmental institution, it is crucial that our processes are transparent and that we are able to explain them to the public in an understandable way.
Improved information technology and social media have given the public ever-increasing access to information, making them more involved and sometimes critical of democratic processes. One example is when a certain treatment is reimbursed in other countries but not in the Netherlands. In order to bridge this democratic gap, it is important that we involve the Dutch people more, e.g. in our decision making, policy making and improvement processes. We are interested in how agencies and institutions in other countries serve the public there and in how they involve the public in their processes.

Sharing knowledge
Not only do we learn from other countries, but many countries look to the Netherlands when it comes to organizing health care. We can help these countries by sharing our experience and knowledge. We regularly receive international delegations that want to find out about the Dutch health care system, our role in that system and our ideas for improvement. These exchanges of information provide valuable lessons, both for the delegation and for us. We have seen an increase in recent years in the number of requests from delegations wanting to visit us. In order to ensure that we will be able to accept such requests in the future from organizations that can benefit most from our knowledge and experience, we have formulated guidelines for assessing such requests.

Another way of sharing our knowledge with other countries is participating in international projects. Decisions as to whether ZIN will participate in new projects will be based on criteria that include whether the goal of the project is in line with our primary tasks and activities.

3 Ambition One: Preserving an affordable health care system

The first of three ambitions stated in ZIN's long term plan 2018-2022 is "Preserving an affordable health care system, for the public as well as the government", with three different underlying sub-goals.

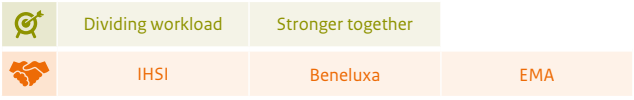
Relevant topics and networks that need our international attention are described below.

3.1 Sub-goal 1: Explaining our processes to the public in an understandable way

ZIN would like to share experiences with other countries regarding this sub-goal, as described in Chapter 2.

3.2 Sub-goal 2: Developing alternatives to our dichotomous HTA-system

3.2.1 Horizon scanning



The Netherlands is actively scanning the horizon to timely anticipate new medicinal products. One of the Dutch corner stones of horizon scanning is that the input comes from health care professionals. However, setting up an international horizon scanning network would be even more effective, as the workload could then be divided and more information would become available. ZIN is participating in the international horizon scanning initiative (IHSI)[11], set up by the Dutch Ministry of Health, Welfare and Sport.

This initiative focus firstly on pharmaceuticals. Besides horizon scanning for pharmaceutical products, options for international horizon scanning of (high risk) medical devices will be explored.

The international initiative on pharmaceutical policy, Beneluxa[12], has 4 domain task-forces, one of which is Horizon Scanning. When it becomes available, Beneluxa will actively use IHSI as its main source of information. ZIN participates in Beneluxa and leads the development of IHSI.

Positions and actions

- ZIN actively encourages the foundation of a fully transparent and publicly accessible international horizon scanning for pharmaceutical products, as well as medical devices.
- International horizon scanning for pharmaceutical products should be beneficial to Dutch horizon scanning in terms of effectiveness.
- The EMA receives information about new products from manufacturers at an early stage. The EMA should make nonconfidential information publicly available sooner. HTA bodies can help determine what information is relevant.
- ZIN is actively participating in setting up ISHI.

11 www.ihsi-health.org
12 www.beneluxa.org

3.2.2 *Real world data (RWD)*

	Obtaining knowledge	Sharing knowledge		
	EUnetHTA	ISPOR	IMI-GetReal	H2020-HTx

For certain medical products, only limited evidence is available at the time of assessment because of, e.g., small patient groups. For all health technology even if sufficient data from randomised clinical trials is available, real world data provides relevant information to evaluate the value and use in daily life. However, when it comes to, e.g., methodology, usability of the data and extrapolating models, certain conditions are essential and must be taken into account. The process of assessment (from selection to the ultimate decision) should be designed in a way that suits to the use of, e.g., RWD. It is therefore necessary to develop other new methodologies for RWD, to explore in which situations RWD is useful. Exploring the possibilities and limitations of using RWD is a focus point in 2020.

Positions and actions

- The use of real world data (RWD) for HTA is inevitable, but developing the methodology, usability of data and extrapolation models needs more attention and will require collaboration with international HTA partners and other international stakeholders.
- RWD should be shared between countries (e.g., registries for orphan drugs or data collection for managed entry agreements).

3.2.3 *Registries*

	Influencing policy	Stronger together		
	EUnetHTA	EMA	IMI-GetReal	ISPOR

In order to obtain real world data, patient registries will become increasingly important be more products (pharmaceutical and medical devices) will be entering the market whose effectiveness is difficult to determine. This might be because of a lack of evidence (no randomised clinical trial and/or small patient groups) or because it is important to monitor effectiveness on a long-term basis (cyclic monitoring) to see if a drug meets expectations in the real world. It is important to know which national and international registries exist, and how national registries might be combined at a European level in order to deal with, for example, the problem of small patient groups.

Positions and actions

- The EMA frequently asks for registries to be set up in order to assess the safety of pharmaceuticals. Governance structures and terms for data accessibility should enable access to data for all stakeholders, with the aim of ensuring equal opportunities for the use of registry data for multiple purposes.
- Registries' data should focus on effectiveness as well as safety, so that HTA bodies can use the data for reimbursement decisions. ZIN supports the current process of qualification of registries by EMA in collaboration with EUnetHTA. Examples are the European Cystic Fibrosis Registry and the European Bone Marrow Transplantation Registry.
- Registries should be set up more at a European level, should be disease based (not drug based), and should be available for use by different stakeholders.
- Health care providers or patients should be the owners of the registries, not pharmaceutical companies or manufacturers of medical devices. If a registry is owned by a pharmaceutical company, the data should be available publicly without unreasonable delay.
- Data collected in registries should be presented according to FAIR (findable, accessible, interoperable, reusable) principles (see section 5.2.1.2).

3.2.4 *Collaboration with regulators (EMA)*

	Influencing policy	Obtaining information			
	EMA	MEDEV	ESIP	HTAi	ISPOR
	EUnetHTA				

The EMA has detailed information about pharmaceutical products that could benefit, e.g., horizon scanning, early dialogues and registries. ZIN would like, through our partners in MEDEV[13], ESIP[14], EUnetHTA[15], HTAi[16] and ISPOR[17], to increase collaboration with EMA so that relevant information becomes available for HTA bodies sooner.

Position and action

- Governance structures and terms for data accessibility set by EMA should enable access to data for all stakeholders, with the aim of ensuring equal opportunities to use registry data for multiple purposes.
- ZIN would like to increase collaboration with EMA in order to have relevant information available sooner for HTA bodies.

3.2.5 *European HTA*

	Dividing workload	Stronger together		
	EUnetHTA	EU HTA regulation	Beneluxa	Malta project

ZIN is the coordinator of EUnetHTA[18], a collaboration between the 28 member states of the European Union. A structural European network needs to be set up in 2020 between European Health Technology Assessment (HTA)-bodies. In 2020 ZIN is supporting the Dutch Ministry of Health, Welfare and Sport at council meetings in order to achieve effective EU legislation on HTA collaboration as a basis for a structural network. This network will jointly assess pharmaceutical products and medical devices.

ZIN is a member of the Beneluxa[19] Initiative. This is a collaboration between Belgium, the Netherlands, Luxembourg, Austria and Ireland that includes HTA activities: joint writing, information-sharing, re-use and recognition. Furthermore, common statements on HTA may be made in the future.

In 2020 ZIN is continuing to support Malta in building an HTA system for pharmaceuticals, as part of the project 'Investing in human capital to create more opportunities and promote the well-being of society'.

Positions and actions

- Countries' participation in the European HTA process and/or use of joint reports should be mandatory. However, the quality of the assessments should be at least equal to that of the Dutch system.
- Manufacturers should be obliged to participate in the European HTA system and deliver the required information.
- ZIN will proactively further develop Beneluxa HTA. This should be done alongside the European HTA (EUnetHTA). This means that European HTA reports should be used within the Beneluxa HTA process.

13 www.medev-com.eu
14 www.esip.eu
15 www.eunethta.eu
16 www.htai.org
17 www.ispor.org
18 www.eunethta.eu
19 www.beneluxa.org

3.2.6 *Mechanisms for pricing of pharmaceuticals and medical devices*

	Stronger together		
	Beneluxa	MEDEV	MoCa

Small companies are often bought up by large firms that then increase prices significantly. In order to keep Dutch health care affordable, it is important that sustainable and affordable prices are paid for pharmaceuticals and medical devices. European legislation on patents and the protection of intellectual property during a transfer should therefore be reconsidered.

To reduce prices, joint negotiations with other countries may be necessary (e.g., through Beneluxa[20]). Furthermore, alternative business and pricing models (e.g., pay for performance and outcome-based payments) need to be explored in order to improve the current Dutch dichotomous model of reimbursement (negative or positive advice about reimbursement).
Related to this is the upcoming EU-USA trade agreement. Draft versions of this agreement need to be carefully monitored in terms of pricing and markets of pharmaceuticals.

The WHO published a resolution stressing the importance of transparency in the pricing of pharmaceuticals[21] ZIN supports this resolution.

Positions and actions

- Smaller manufacturers of (orphan) drugs should, within legal boundaries, be actively supported in order to prevent large companies from dominating markets and setting (exorbitant) prices.
- Where deemed relevant, ZIN will contribute to discussions on legal frameworks for intellectual property, reference pricing mechanisms and alternative payment models at both a European and international level (e.g., EU-USA trade deal).
- ZIN supports the WHO resolution for more transparency in the pricing of pharmaceuticals.

3.2.7 *Price and reimbursement methods*

	Sharing knowledge	Obtaining knowledge				
	ISPOR	HTAi	H2020 - HTx	G-I-N	GINAHTA	EUnetHTA

Different countries have various eligibility models for reimbursement coverage (e.g., relating to products, diseases population-groups, consumption-based). These different models and their consequences are relevant when reviewing our current dichotomous reimbursement model (negative or positive advice about reimbursement). Access to affordable medicines and medical devices must remain on the political agenda in order to guarantee the sustainability of European health care systems and the cost-effectiveness of these medicines and medical devices. At the same time, national pricing and reimbursement mechanisms must be strengthened to ensure the sustainability of health care systems and patients' access to care. Payers have a key role to play in maintaining and safeguarding access for all insured persons to affordable and high-quality health care, including medicines, medical devices and other health care innovations (e.g., ehealth developments).

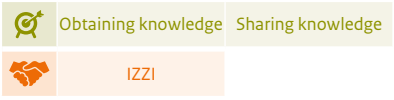
20 www.beneluxa.org
21 *"Improving the transparency of markets for medicines, vaccines, and other health products", 28 May 2019 (WHO: A72/A/CONF./2 Rev 1).*

One of the sub-goals of ZIN as defined in the long-term plan for 2018-2022 is assessing the extent to which our reimbursement method is future-proof. Health care in the insured package must comply with the 'established medical science and medical practice' criterion. This criterion demands a clear yes or no answer. However, a 'conditional yes' may sometimes be more desirable. This would make it possible to reimburse health care that does not completely fulfil the statutory criterion, on the condition that data is collected about the effectiveness of that care. ZIN therefore supports the development of new assessment and appraisal models that could be applied for more flexible approaches to reimbursement decisions.

Position and action

- The dichotomous reimbursement method (negative or positive advice about reimbursement) should be adapted by introducing other types of reimbursement decision methodologies. Development should preferably be done in international collaborations.

3.2.8 *Indication-wide assessments*

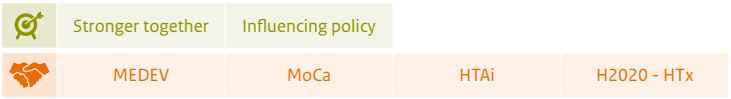


A new model of pharmaceutical assessment is indication-wide assessment, in which the assessment focuses on a certain illness or indication (disease models), including all pharmaceutical products for treating that illness or indication. This more holistic approach has the advantage that the assessment compares multiple and different (pharmaceutical) products designed for that indication, making the assessment broader and therefore more effective. Furthermore, assessing multiple products related to a certain illness or indication creates a more cyclic evaluation of the health insurance package, thus contributing to appropriate care. Some countries, e.g., Sweden, France, the UK, and the Netherlands, are experimenting with this approach and it is important to learn how disease models might be used for package management and reimbursement assessments. This model could also be applied to medical devices. This approach has a strong link with appropriate care (see section 3.3).

Position

- The use of indication-wide assessments should be a more common method of assessment for reimbursement decisions, encouraging a more cyclic health package management approach based on appropriate care methodologies. Methodologies should preferably be developed in international collaborations.

3.2.9 *Orphan drugs*



An increasing number of drugs are orphan medical products that target small and very smallpatient groups.

Because of the smal patient groups, there is a lack of relevant or valid outcome measures and long-term effectiveness is unknown. Limited or no evidence is available about the added benefit and value. Also, orphan drugs are often expensive. Current frameworks for assessment or appraisal may need to be studied to see whether adaptations may be needed to allow better assessment of orphan drugs. European registries need to be used and more collaboration with the EMA and European Reference Networks is needed.

Furthermore, greater numbers of drugs are being defined as orphan drugs, which gives manufacturers years of exclusivity and opportunities to demand higher prices. In this context, orphan drug regulations are sometimes misused. What frequently happens after negotiations is that the number of indications

is increased, leading to a larger group of patients being eligible for reimbursement, but still at the initial high orphan drug price. Collaboration between countries is necessary to stop such mechanisms, e.g., by limiting patent periods when extra indications are added. The orphan drug regulations should therefore be evaluated and amended.

Position and action

- Orphan drug regulations should be evaluated and amended to stop mechanisms by which those regulations can be misused. ZIN wants to participate in these discussions through its relevant networks.

3.2.10 *Advanced Therapy Medicinal Products (ATMP's) and genomics*

An increasing number of potentially curative interventions are being developed, e.g., Advanced Therapy Medicinal Products (ATMP) such as somatic cell therapies, tissue-engineered products and gene therapies. These products frequently have an orphan drug indication.

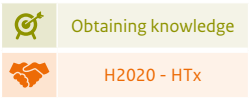
Little is known about their long-term effects and prices are often extremely high. HTA is challenging due to the limited amount of evidence, the small small patient populations and uncertainty about the long-term effectiveness.

ZIN is taking steps at both the national and international level to develop methodologies and approaches to the assessment, appraisal and reimbursement of potentially curative interventions. The development and refinement of such approaches is done in collaboration with other HTA agencies and payer organisations.

Position and action

- Methodological approaches, both in HTA as well as in pricing and reimbursement, should preferably be developed in international collaborations.

3.2.11 *Personalised medicine*



Personalised medicine focuses on treatments tailored to individual patients. In oncology, for example, increasing knowledge about mutations in genes is leading to an increased number of pan-tumor indications. Development of these medicines is increasing, as is their off-label use. It is important to develop methodologies further for the assessment appraisal and reimbursement schedules for these kinds of products. ZIN interacts closely with other HTA bodies in Europe on this matter.

Position

- HTA-methods and reimbursement models should be suitable for personalised (or precision) medicinal interventions, and developed in an international context (Horizon 2020 project HTx).

3.2.12 *Medical Devices Regulation (MDR)*

	Influencing policy	Sharing knowledge		
	ESIP	EUnetHTA	HTAi	ISPOR
	INAHTA	H2020 - HTx	IMI Getreal	GRADE

The pace of development of new medical devices is increasing. Every year, a growing number of companies are introducing devices and technical modifications of existing medical devices onto the market and expectations are that this trend will continue in the next few years. Furthermore, up till now the notification process was neither transparent nor particularly solid. For this reason a new regulation on medical devices and in-vitro diagnostics came into force on 26 May 2017, adopting new requirements for medical devices and in-vitro diagnostics. All relevant medical devices need to comply with the new rules by no later than 26 May 2021 (2022 for in-vitro diagnostics and 2024 for Class I products). This new regulation aims to improve the safety of medical devices and the transparency of the market entry system in Europe, e.g., by getting member states to implement a harmonised notification process for notified bodies, and by applying the new scrutiny mechanism. Transparency, with a wholly or partly publicly accessible European database on medical devices (EUDAMED), has a key role in ensuring the safety and traceability of health technology.

Implementation of this new regulation and monitoring its consequences is a focus point of the Dutch Ministry of Health, Welfare and Sport. ZIN is following the implementation process, in relation to its tasksin health package management and the quality of care.

The new regulation concerns market entry only and does not provide for a centralised authorisation procedure for the reimbursement of high-risk medical devices.

Because of the increased pace of the introduction of new medical devices onto the market, the option of European horizon scanning for medical devices needs to be explored. The methods used for pharmaceutical horizon scanning may be wholly or partly adopted. It is also important to pay attention to post marketing surveillance (PMS) after introduction.

A new regulation about in-vitro diagnostics, the IVDR, will take effect on 26 May 2022. The consequences of this new regulation need to be investigated.

Besides guaranteeing the safety of medical devices and new technologies, other relevant topics for ZIN for 2020 regarding medical devices are:

- Faster availability and patient access to relevant innovative medical devices, without losing sight of safety;
- Focus on more and better research when it comes to medical devices;
- Focus on narrowing the evidence gap between research that needs to be done to get a CE mark based on the MDR (May 2021), and assessing the effectiveness of medical devices (in particular those with a medium and a high risk).
- Comparing the EU HTA proposal against current ZIN and EUnetHTA methods, for medical devices as well.
- Intercountry comparison of funding and payment mechanisms for the reimbursement of innovative medical devices.

Positions and actions

- Horizon scanning should take place at a European level, not only for pharmaceuticals but also for medical devices and health care innovations (e.g., telemedicine, robotics, AI, wearables), to anticipate the introduction of these new devices and provide timely market access.
- A centralised authorisation procedure for the market entry of high risk medical devices (such as implants) is necessary to anticipate the growing number of new medical devices. At the same time, national pricing and reimbursement mechanisms must be strengthened to ensure the sustainability of health care systems and patients' access to care. This centralised authorisation procedure should be obligatory in European procedures, but not in national procedures.
- The creation of a European database on medical devices (EUDAMED) that is fully accessible to patients and health care providers is crucial. Since EUDAMED is delayed, it should become clear what the (temporary) alternative is.
- Although reality is complex, it is desirable that clinical evidence is available for high-risk medical devices (classes IIb and III, IVD: C and D) at the time of market approval (CE marking) if it is needed for reimbursement decisions.
- Patient relevant data (at least for the treatment approach as such, if not for a specific product) should be available at the time of market access. Data that may be missing should be provided by trials set up by manufacturers. These obligations should be communicated or mandated directly by the responsible notified bodies when setting up the PMCF, and should be part of any consultation of manufacturers, regardless of whether this consultation is done by EUnetHTA or another body.
- Awareness of the importance of medical devices as part of health care should be increased on a national and an international level.
- Consequences of the new regulation about in-vitro diagnostics, the IVDR, need to be investigated. This new regulation will take effect on 26 May 2022.

3.3 Sub-goal 3: More appropriate care

	Obtaining knowledge	Sharing knowledge	
	IZZI	HTAi	EUnetHTA

In the Netherlands the health care system aims to provide appropriate care to all members of the public who need it. Appropriate care (*Zinnige Zorg*) aims to provide care for patients with little with little cost wastage, which will help to make the health care system sustainable. The terms *Gepast gebruik, zinnige zorg* and value-based health care are almost synonymous with appropriate care and are used interchangeably

Appropriate care is one of the core focuses of ZIN. This approach is relatively new, not just for ZIN but for most governmental agencies as well. Organisations such as HTAi, IHI, the OECD, the WHO, Wennberg and Dartmouth are interested in this concept. It is also getting attention at a EU level. However, in comparison with medicines and medical devices, less attention is being paid to this theme on the international scale. Further development and international orientation will help to enhance methodologies to implement appropriate care in actual Dutch health care practice. International exchanges can also accelerate ongoing improvement programmes, especially in what is referred to as the "in-depth analysis phase" and in the "implementation phase", where ZIN can profit from other countries' analyses and experience (where available).

Position

- Zinnige Zorg is aimed at achieving more evidence-based care (EBM) in practice. To gain a better understanding of good EBM care and how to provide it in real-life, it is fundamental that relevant stakeholders (such as patient organisations, health care professionals and insurance companies) should be involved.

3.3.1 *IZZI network*


Obtaining knowledge Sharing knowledge


IZZI

ZIN has initiated an informal international network focused on appropriate care, IZZI (International Zinnige Zorg Initiatives), where various national health care organisations and health care advisory organisations gather to discuss appropriate care initiatives. More information about the IZZI network can be found in chapter 6.

It is desirable to further strengthen the IZZI network through: (1) Continuing the biannual conferences; (2) Intensifying communication between members and (3) Connecting to other initiatives and considering adding more members. This can let ZIN profit from other countries' experience.

As one of the main goals of IZZI is to develop our methodology, information about the approaches and methodologies other organisations/countries use to identify, research and analyse appropriate and inappropriate care are very helpful. Information that can help to strengthen the IZZI network (e.g., possible interested or interesting partners, contacts organisations, countries and/or conferences) can be shared with the IZZI secretariat, LSicking@zinl.nl.

Position and actions

- ZIN wants to explore the possibility of becoming a member of relevant international networks and visiting relevant conferences (e.g., Wennberg Institute, Harvard, Dartmouth, Gilbert Welch, Cochrane).
- The *Zinnige Zorg* approach will be presented at relevant conferences (e.g., IHI and HTAi) and networking activities will be expanded (e.g., OECD, WHO).
- ZIN actively participates in relevant EU initiatives (Brussels), such as Friends of Europe of FIPRA and will work with EUnetHTA on appropriate care initiatives.

3.3.2 *Promoting appropriate introduction of health care innovations*


Obtaining knowledge

The Dutch health care package system allows an 'open' entitlement to the reimbursement of many innovative forms of care. After market entry, the lion's share of new therapeutic devices, interventions and digital technologies flows into the statutory insured package without prior assessment. This is causing an increase in reimbursed interventions that have not undergone prior assessment, leading to potential unwanted consequences such as adverse effects and inefficient use. In 2020 ZIN is investigating options for proactively promoting the appropriate introduction and up-scaling of new health care technology as well as options for better discriminating between innovations that actually improve care at the patient level and those that lead to inappropriate care and unnecessary costs. With regard to these research lines, studying and comparing countries with different health systems will be considered in 2020. This includes assessment and reduction of the environmental impact of health care innovations.

Position and action

- No specific position was formulated. ZIN's position will be determined in 2020 when research lines will be considered.

4 Ambition Two: Better care available faster

The second of three ambitions as formulated in ZIN's long-term plan for 2018-2022 is "Better care available faster by accelerating the cycle of measurement, knowing, learning and implementing in health care".

Relevant topics and networks that need our international attention are described below.

4.1 Sub-goal 1: Encourage the use of patient reported data


Obtaining knowledge | Sharing knowledge


ICHOM | Nat. Health Agencies | EIN

Patient reported data (e.g., PREM's and PROM's) feeds the cycle of measurement, knowing, learning and implementing in health care (the circle of quality). Insight into patients' experiences and the outcomes of care can function as important feedback for further improving the organisation of health care and support for patients and professionals alike in shared decision-making and in delivering appropriate care.

4.1.1 *Encouraging the development and implementation of guidelines and indicators*

Appropriate care is care that best suit patients' needs while taking account of their wishes and health situation and context Due to differences in patients' wishes needs and contexts, appropriate care can mean different things to different patients, or even to the same patient at different times. Moreover, personal, cultural, organisational and technological developments result in a continuously evolving definition of 'appropriate care'. Shared decision-making between patients and professionals is of great importance in realising appropriate care in clinical practice. Furthermore, the best way to pursue appropriate care is by continuously learning from and improving the practice of health care by all stakeholders. Relevant stakeholders in the Dutch context are patients, health care providers and insurers. Outcome information as an aspect of measuring the quality of health care, of which patient-reported data is an important element, is crucial for gaining a clearer picture of the perceived quality of care and thereby supporting all relevant stakeholders in their participation.

Agreements about how to organise, deliver and measure health care have been formulated in guidelines[22], along with indicators for measuring the specific quality of the care delivered. In order to improve the quality of Dutch health care further, ZIN therefore actively encourages the coherent development and implementation of these guidelines and indictors by relevant stakeholders and publishes data on the delivered quality of care on the website *Zorginzicht*[23]. These guidelines, indicators and data play a vital role in the realisation and operation of quality cycles aimed at continuously improve the quality of care. ZIN defines the quality of these guidelines and indicators with a criteria assessment framework (the *Toetsingskader*), which encourages the participation of all relevant stakeholders and the coherent development and implementation of these instruments. Some of these criteria explicitly encourage relevant stakeholders to develop indicators for measuring patient reported data or to develop existing indicators further ZIN also publishes - on the website *Zorginzicht*[24] - tools to support the development of these indicators. After meeting the criteria of the *Toetsingskader* indicators are published in an overview (the *Transparantiekalender*) of all indicators for which care providers are obliged to provide data on the delivered quality of care[25]. Publishing this data on *Zorginzicht* is how ZIN aims to encourage to stimulate the use of patient-reported data.

It is important that stakeholders try to find a balance between on one hand the number of indicators developed to measure and stimulate the quality of care on the on hand, and the administrative burden of these indicators on daily clinical practice, on the other. Therefore, in collaboration with stakeholders, in recent years ZIN has worked to decrease the total number of indicators, while stimulating the

22 *In the Netherlands, guidelines are described as quality standards that describe, for every disorder, how an indication is determined, what care is available and how the care processes are organised. Patient centeredness is key in these guidelines.*
23 www.zorginzicht.nl/openbare-data
24 www.zorginzicht.nl/ontwikkeltools/prom-toolbox/prom-cycle-summary-in-english
25 www.zorginzicht.nl/ondersteuning/transparantiekalender

development of (patient-reported) outcome indicators. ZIN stresses the importance of developing indicators that make use of data registered in daily clinical practice as far as possible, in order to prevent a further increase in the burden of registration for health care providers.

Furthermore, to achieve better care faster, it is important that guidelines, indicators and other tools (such as decision aids and recommendations for introducing effective innovations) are applied in health care practice. It is therefore necessary to encourage implementation strategies. Some of the criteria of the Toetsingskader encourage relevant stakeholders to develop 'implementation plans. In order to explore and develop further means of encouraging implementation, ZIN initiated the National Implementation Collective (NIC), a national community of practice for implementation specialist/change agents.

In order to keep the quality of the guidelines up, the quality standards and indicator criteria in the Toetsingskader need to be periodically evaluated and updated. When doing this, it is important that ZIN remains informed about trends and changes in the organisation and the methodology for developing guidelines, quality standards and indicators, as well as tools that support the development and implementation of guidelines, quality standards and indicators. More general topics in health care, such as the introduction of shared decision-making and value-based health care, may also influence the criteria of the Toetsingskader. Many of these trends and developments are developed in close collaboration with other countries.

Positions and actions

- Guidelines are necessary instruments in defining the high quality of care within a health care system.
- Outcome information about the quality of health care, whereby patient-reported data is crucialfor getting a better picture of the quality of care and thereby supporting patients, professionals and insurers in their participation.
- Shared decision-making supported by patient-reported data is crucial for choosing appropriate care by patients and professionals by gaining an understanding of outcomes of various possible interventions.
- Professionals, patients and/or patient organisations should all be involved in determining the selection of relevant outcomes and in the development and selection of instruments that measure those outcomes.
- Patient-reported data is crucial for realising a quality cycle in health care practices and at a national level for further development of quality instruments.
- Guidelines, HTA reports and quality indicators are not the end product of ZIN, but mark the start of an implementation process. Knowledge-sharing and building a socio-technical implementation infrastructure are important for quality improvement. The National Programme on Outcome Data (for Shared Decision Making) focuses on these topics in the Netherlands.

4.2 Sub-goal 2: Guidelines should address appropriate care

In the Netherlands the health care system aims to provide appropriate care to all members of the general public who need it. Appropriate care can be defined as providing patients with effective and tailored care for patients, with the least possible cost wastage, thus helping to keep the health care system sustainable.

4.2.1 *Assessment framework (Toetsingskader)*

Obtaining knowledge	Sharing knowledge	
GIN	Nat. Health Agencies	IHI

As mentioned in the previous section ZIN encourages the use of guidelines and indicators through a framework of criteria (Toetsingskader). Some of these criteria promote efficiency by encouraging the relevant stakeholders to determine and agree on preferred care interventions for specific patient groups in specific situations while preventing unnecessary treatment or a decrease in quality of life and the use of resources. Furthermore, given that the results of possible interventions are similar, ZIN encourages patients and professionals to select the most sustainable option in terms of the consumption of energy and use of raw materials and creation of pullution.

Position

- Apart from the effectiveness of interventions, relevant stakeholders (patients, health care providers and insurers) should also consider efficiency when developing guidelines, in order to keep the health care system affordable as well a retaining a healthy living environment.

4.3 Sub-goal 3: ZIN's advice process is up-to-date and ready for innovative health interventions

Relevant topics, positions and networks for this sub-goal are described in sections 3.2.1 and 3.2.2.

5 Ambition Three : Better custom made decisions based on relevant data

Health care data has specifically caught Europe's attention, as described in the Mission Letter from Ursula von der Leyen (President of the European Commission) to Stella Kyriakides, Commissioner-Designate for Health[26] and in the propositions for the EU health agenda 2020-2025 made by the Dutch government[27].

The third of three ambitions stated in ZIN's long-term plan for 2018-2022 is "The public is are able (together with their health care providers) to make better custom-made decisions about their own health: they will have access to relevant information about a health care offer, its quality and treatment options".

Relevant topics and networks that need our international attention are described below.

5.1 Sub-goal 1: Clarify what information is relevant for patients

ZIN follows the international initiatives of the National Programme on Outcome Data (for Shared Decision Making), such as 'Patients like me', ICHOM and Thuisarts.nl.

Position and action

- No specific position was formulated other than that information for patients should be clear and understandable.

5.2 Sub-goal 2: Unambiguous and reliable information-sharing

Obtaining knowledge | Sharing knowledge

Sharing unambiguous and reliable information is a big topic in 2020 and it will be even bigger in the future. Improving the sharing of information about health care is on the agenda of many European countries and has a high priority in the Netherlands too. Improving sharing of information will result in better quality care at lower costs. Collaboration between the different stakeholders in different countries is necessary to realise the ambitious goal of improving information sharing in health care.

There are new innovative ways to improve the exchange of information and data. ZIN sees promising developments, from data *exchange* to data *visiting*. ZIN wants to understand the capabilities of those innovations, the impact they will have and the possible opportunities and threats of these new innovations. A clear data strategy is needed that will help to find the relevant innovations. But without improving the interoperability, improving information-sharing will be impossible.

The international focus of ZIN for ambition three will therefore be on[28]:

- Interoperability
- Data strategy
- Innovation

5.2.1 *Interoperability*

Interoperability is an important topic that is on the agenda of the EU and is part of the objectives of the Information Council (*Informatieberaad*) and ZIN's long-term policy plan for 2018-2022. Information exchange issues are well-known, take the thousands of unnecessary deaths each year due to medication errors, for example[29]. These medication errors are the result of an incomplete or incorrect medication overview. For the collection and comparison of quality data and other information for the public it is

26 https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-stella-kyriakides_en.pdf
27 'The Netherlands' propositions for the EU health agenda 202002025', https://www.permanentrepresentations.nl/documents/ publications/2019/06/13/the-netherlands'-propositions-for-the-eu-health-agenda-2020-2025
28 In a way interoperabiliy, data strategy and innovation are connected.
29 www.nporadio1.nl/onderzoek/15588-dood-door-medicatiefouten

important that agreements are made about the exchange of information. Other countries are facing similar problems. However, some countries have put together practices, for example Estonia, Sweden, Norway, Finland and Denmark.

To ensure correct interoperability, the EIF composed an interoperability framework. The new European Interoperability Framework (EIF)[30] describes 4 layers of interoperability:

- Legal interoperability: The EIF proposes that EU and national legislation and policies must be made clear, coherent in respect of one another and make good use of technology[31].
- Organisational interoperability: The EIF encourages public administrations to simplify their organisations, to streamline their processes and to listen to the needs of the business community and the general public.
- Semantic interoperability: The EIF calls upon public administrations to structure their data in commonly agreed formats
- Technical interoperability: The EIF promotes the sharing and reuse of common infrastructures, services and IT-systems.

For every layer, ZIN looks to front-running countries and explores the best practices in those countries to learn from those practices and - where applicable – try to implement them in the Netherlands. ZIN looks for collaboration with countries to learn from the front-runners and to share our knowledge with countries who want to learn from us (for example our sustainable information system).

Improvement in interoperability is necessary and can be achieved by focusing on:

- Standardisation
- Models and frameworks
- Architectural principles (Such as *FAIR* and "One-time registration, multiple use")

5.2.1.1 *International standards*

Stronger together

Using open and international standards helps to improve interoperability. It is important for ZIN to follow international developments, and simultaneously to encourage international harmonisation endeavours.

Position and action

- Dutch health care should, where possible, be aligned with international standards (ontologies and/or classifications like SNOMED or technical standards such as W3C semantic web), instead of creating our own national standards. ZIN follows international developments.

5.2.1.2 *FAIR data principles*

Sharing knowledge

The volume and complexity of the data are growing at exponential rates. There is an increasing acknowledgement of the importance of making health care data findable, accessible, interoperable and reusable (FAIR). Following the FAIR principles (and the accompanying good data stewardship) will help to improve the data sharing The Netherlands is one of the front runners in adopting the FAIR principles. ZIN was involved in recent FAIR projects, knowledge to pilots using FAIR data. ZIN wants to share knowledge[32] (lessons learnt) and looks to collaborate with international partners. ZIN seeks international collaboration and shares knowledge on FAIR principles Findable, Accessible, Interoperable and Reusable and FAIR data.

30 ec.europa.eu/isa2/eif_en
31 The EIF structure also describes 12 underlying principles and 47 recommendations for improving interoperability
32 ZIN participated in the second Go FAIR International Implementation Networks meeting on 23-24 January 2020 in Hamburg, https://www.go-fair.org/events/2nd-go-fair-international-implementation-networks-meeting/

Position and action

- In international projects, where possible, the FAIR principles should be leading when storing and sharing data. ZIN encourages this in projects in which it is participating.

5.2.1.3 *One-time registration, multiple use*

 Obtaining knowledge | Sharing knowledge

One-time registration and multiple use of data is one of the main topics of the Information Council (objective number 4) because of the current registration burden on Dutch health care and because one-time registration increases the reliability of information. Technology permits the combination of a growing number of data sources, even if the data is unstructured. ZIN has already done a number of pilots with innovations that can facilitate multiple use of one-time registered data, such as FAIR data, the Personal Health Train or the block chain. Such innovations and shared architectural principles (following the FAIR principles) are also being developed by other countries. ZIN wants to explore the initiatives taken by front-running countries to see what technical solutions other countries are investigating or implementing, and to collaborate with those countries to share knowledge on this subject and help one another with this important architectural principle. ZIN uses the lessons learnt to determine future positions on this subject.

Position and action

- In international projects focusing on the use of data ZIN is a key link between stakeholders when sharing minimum conditions for the one-time registration, multiple use principle.

5.2.2 *Data strategy*

 Obtaining knowledge

 H2020 - HTx | IMI GetReal II

A growing quantity of data is being collected, both nationally and internationally. There are a lot of developments and opportunities for using data. It is therefore important to have a clear data strategy that will help to strengthen conditions for the proper and responsible use of data in health care.

Giving meaning to data can lead to useful information. Correctly operationalising data, allows it to be used for important tasks of ZIN. There are already international initiatives focusing on the use of big data. ZIN is exploring international initiatives and learning from the good practices of other countries. This could benefit the activities in Appropriate Care, health package management (HTA), quality (shared decision-making), IMI GetReal II, HTx, the use of real-world data and Horizon 2020.

In its the Data policy plan for 2020 ZIN describes:

- *Improve what we do*: we promote cooperation and consistency between our existing tasks and the growing data expertise activities.
- *Improve how we perform our work*: build on the durability of the information and data landscape.
- *Innovate and better understand the impact of digital transformation*: monitoring national and international data strategy developments, public-centric design of innovative business cases and experimentation.

In order to remain in touch with international data strategy, ZIN follows international trends, developments and projects in digital transformation, medical technology, eHealth, big data, AI, federated distributed learning, etc. Developments in these areas happen fast and it is important to keep up in order to support individual patients with data-based developments.

Position and action

- Because of fast-growing developments in the use of health care data, ZIN has not yet formulated statements on this topic, other than that developments in the use of big data in health care should be monitored. Given these developments, in parallel to and based on its watch-dog function, the role of ZIN will be explored in the meantime.

5.2.3 *Innovation*

Obtaining knowledge

The latest technological developments (especially when combined with a clear data strategy and good conditions for interoperability) will speed up the number of innovations in health care (as described in section 3.3.2). This digital transformation will not only bring many great opportunities for improving health care (personalised medicine, AI, medtech, robots), but also some major challenges (privacy, ethical issues, security).

To keep up with the latest developments in innovations, ZIN follows international trends and developments in data innovation, maps out international innovative initiatives and looks for good practices from which ZIN can learn, in order to help stakeholders and individual patients. ZIN is prepared to participate in initiatives or connect with other initiatives that are relevant for ZIN.

A good example of a data-driven innovation in international collaboration is the Maastro-project. In this project a Personal Health Train (PHT) is using an international network of data sources from hospitals in different countries (Switzerland, Germany, Luxemburg and the Netherlands). The data remains in its original location and the PHT visits the data sources and executes tasks relating to analytics. This lets the hospitals remain in control of their data and lets them decide what which data will be analysed for which specific purpose and by whom.

Participating in data-driven initiatives (following the 5D-method[33]) will help ZIN to:

- Create awareness in the internal organisation.
- Recognise the impact of the innovation sooner.
- Recognise the risks of the innovation.
- Maps out the conditions (also legal conditions) that are necessary for the innovation.

Position and action

- No specific position was formulated. To keep up with the latest developments in innovations, ZIN follows international trends and developments in (data)innovation, maps out international innovative initiatives and looks for good practices from which ZIN can learn.

5.3 Sub-goal 3: Focus on information that is relevant for patients

Improving the exchange of information will help to get the relevant information to patients. This was specified in section 5.2.

33 *In right order: Detect it, Think of what it is, Do it, test it, pass on.*

6 Networks and projects

ZIN participates in a variety of international networks and projects, each of which is described below. If a certain network or collaboration focuses on a specific topic, that network is listed above the topic described in Chapter 3, 4 and 5.

Beneluxa (www.beneluxa.org)


Beneluxa

Objective: HTA cooperation and information exchange.
Agenda:
- Short statements, collaboration on horizon scanning and early HTA.
- Doing assessments together, dividing the work load although assessment by EUnetHTA is preferred.
- More information sharing (practically about processes, and strategically).
- More information-sharing about products (between assessors).
- More combined price-negotiating (and joined assessement in order to realise this).
  Horizon scanning at a European level.

EMA (European Medicines Agency, www.ema.europa.eu)


EMA

Objective: To take into account the reimbursement as soon as medicines are registered.
Agenda:
- Do not allow medicines approval too early.
- Cooperation with EMA.
- Take the relevant stakeholders into account when assessing.
- Registers with access to raw data for HTA and clinicians.
- Better European public assessment reports and summaries of product characteristics.
- More and earlier information sharing for horizon scanning.
- Early multi-stakeholder dialogue.

EUnetHTA (www.eunethta.eu)


EUnetHTA

Objective: To support collaboration between European HTA organisations that brings added value to health care systems at a European, national and regional level.
Agenda:
- Supporting the efficient production and use of HTA in countries across Europe.
- Providing an independent and science-based platform for HTA agencies in countries across Europe to exchange and develop HTA information and methodology.
- Providing an access point for communication with stakeholders to promote transparency, objectivity, independence of expertise, fairness of procedure and appropriate stakeholder consultations.
- Developing alliances with contributing fields of research to support a stronger and broader evidence base for HTA while using the best scientific competence available.

EU HTA regulation


EU HTA regulation

Objective: Achieving effective EU legislation on HTA collaboration as a basis for a structural network.

European Implementation Network (www.einnetwork.org)

EIN

Objective: Working on implementation at European level.
Agenda:

- Further development and international orientation to enhance further development of effective theory and insights for implementation (especially those for daily work in practice) and to encourage implementation in complex adaptive systems. Learning and development is an important theme to work on.

ESIP (European Social Insurance Platform, www.esip.eu)

ESIP

Objectives and agenda:

- Informal information-sharing about, among other things, European affairs and developments in HTA and medical devices
- Assessing together based on early in-depth information from the EMA.
- Influencing relevant European agendas.
- Obtaining information about (HTA and other) practices in other countries.
- Cluster assessments, disease models.

G-I-N (Guidelines International Network, www.g-i-n.net)

G-I-N

Objective: to lead, strengthen and support collaboration in guideline development (including technology assessments and appraisal), adaptation and implementation.
Agenda:

- Facilitating networking, the exchange of knowledge and improving methodology.
- Promoting excellence, helping to create high-quality clinical practice guidelines that foster safe and effective patient care.
- Sharing a wide variety of support tools and publications to enhance guideline development and knowledge-transfer.

GINAHTA (Guidelines International Network Heath Technology Assessment, www.g-i-n.net/working-groups/ginahta)

GINAHTA

Objective: to explore common methods and facilitate collaboration and the sharing of products between the HTA (represented by INAHTA) and guideline communities (represented by G-I-N).
Agenda: The working group acts as a facilitator to join efforts of the HTA and the guideline community by:

- Identifying common methods (including assessment and appraisal methods).
- Identifying complementary aspects between the products of both communities.
- Detailing a platform for promoting collaboration and sharing products.

GRADE working group (www.gradeworkinggroup.org)

GRADE

Objective: to improve and extend GRADE methodology (technology assessment and appraisal) and to spread the use of GRADE methodology in health guidelines, HTA and systematic reviews.
Agenda:

- Creating supporting and collaboration opportunities.
- Helping GRADE networks/centres (e.g., Dutch GRADE Network) with training, promotion, dissemination and implementation of GRADE.
- Providing methodological support for national, regional or professional organisations.
- Specific project groups on e.g., Non-Randomized Studies, Economic Evaluations (cost-effectiveness).

Horizon 2020 HTx (Health Technology Exchange)

H2020 - HTx

Objective: Development of next generation HTA models.
Agenda:
- To development HTA methods that would fit to personalised (or precision) medicine.
- To test and implement these methods in the practice of HTA bodies.

HTAi (Health Technology Assessment international, www.htai.org)

HTAi

Objective: To foster international scientific collaboration on HTA.
Agenda:
- Further development of HTA methods, for example, deliberative processes in HTA.
- Interaction with stakeholders such as patients and technology producers, on HTA methods and implementation (HTAi Policy Forum).
- Sustainable health care systems.

IHSI (International Horizon Scanning Initiative, www.ihsi-health.org)

IHSI

Objective: Horizon scanning aims to highlight important pharmaceutical and medical technology innovations before they reach the market by continuously gathering data and analysing research and literature. This gives a better picture of expected costs and allows timely decision-making and (joint) price negotiations.
The Beneluxa Initiative on Pharmaceutical Policy aims to seek successful ways of collaborating on pharmaceutical policy. One of its goals is to set up a systematic approach to horizon scanning for pharmaceutical products through IHSI.

ISPOR (The Professional Society for Health Economics and Outcomes Research, www.ispor.org)

ISPOR

Objective: To further develop tools for health economic assessments and outcome research.
Agenda:
- Development of methods of RWE and their implementation in HTA practice.
- Refinement of health economical models and their use in decision-making.
- Increase interaction between method developers, for example, academics and consultancies, and users such as HTA bodies.

INAHTA (International Network of Agencies of Health Technology Assessment, www.inahta.org)

INHTA

Objective: To enhance collaboration between international HTA bodies.
Agenda:
- To facilitate the exchange of methods and processes between HTA bodies world wide.

IZZI (International Zinnige Zorg Initiatives)


IZZI

ZIN has initiated an informal international network focused on appropriate care, IZZI (international Zinnige Zorg Initiatives), where various national health care organisations and health care advisory organisations gather to discuss appropriate care initiatives. Currently the IZZI network has eight permanent members (Belgium, Germany, France, Austria, Spain, Italy, Switzerland and the Netherlands). The network has the following objectives:

- Learning about methodologies. How to research appropriate care and how to find indications for inappropriate and appropriate care.
- How to realise improvements (implementation). Where restrictions exist, how to overcome restrictions, how to cooperate with and within the field.
- Addressing specific improvement projects, on diseases, devices, systems.
- Leading. Inspiring other countries with regard to the Dutch appropriate care method.
- Finding support among the community.

IMI GetReal II (Innovative Medicines Initiative, www.imi-getreal.eu)


IMI GetReal II

Objective: To improve methods for the use of RWE.
Agenda:

- To improve methods for using RWE on the basis of IMI-GetReal I.
- To implement and test these methods in national and international HTA settings.
- To develop a sustainable model for IMI GetReal at the end of the IMI funding (2020).

Investing in human capital to create more opportunities and promote the well-being of society (EU funds for Malta)


Malta

Objective: To help Malta organise processes for health care quality and the reimbursement of medicines.
To support processes for health care quality in Maltese hospitals.
To facilitate a new system for the assessment and appraisal of medicines in Malta.

MEDEV (Medicine Evaluation Committee, www.medev-com.eu)


MEDEV

Objectives and agenda:
Informal information-sharing about, among other things, European affairs and developments in HTA regarding pharmaceutical products.

MoCA (Mechanism of Coordinated Access to orphan medicinal products, www.moca)


MoCa

Objective: Payers, HTA bodies and patients speak with small orphan drug manufacturers at an early stage (early dialogues).
Agenda:

- Early detection of new technologies.
- Structured cooperation with EU patient organisations.
- Early orientation about new and existing reimbursement models.
- The possibility to connect with the regulation on promising innovative care in NL.
- Creating conditions for price negotiations at national and international (Beneluxa) levels.
- Practice with multi-stakeholder cooperation.

Network of health agencies (to be founded)


Nat. Health agencies

Objective: To develop and expand a permanent framework of cooperation under which members will develop mutually beneficial programs to improve and harmonize health performance and quality.
Agenda (to be determined):

- To share and utilise technical expertise in developing common approaches and methodologies, integrated and harmonised with the national systems.
- To provide shared technical approaches and support for defining the national policies and regulations pertaining to health systems.
- To harmonise the implementation of EU recommendations on health and clinical risks.
- To identify opportunities for common improvement projects on health systems' performance, health care quality and safety and to jointly pursue such projects.
- To approve shared publication of printed materials intended for public distribution regarding systems performance, health care quality and safety.
- To coordinate activities designated to share common best practices.
- To collect best practices in education and training in the listed areas, in order to define shared training curricula to be used in the different countries.
- Annual meeting to continue comparison and sharing on results of all the activities mentioned.

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